

**REMARKS**

Applicant appreciates the Examiner's review of the present application and respectfully requests reconsideration based on the previous amendments and following remarks. Applicant asserts that this response puts all claims in form for allowance, or alternatively more clearly defines the issues for appeal. Claims 13-25 are pending in the present application.

35 U.S.C. §112, second paragraph

The Examiner has rejected Claims 13-25 under 35 U.S.C. §112, second paragraph, as being incomplete for omitting an essential element. Applicant has amended Claim 13 to provide recitation of the element requested by the Examiner. By the same amendment, Applicant has inserted back into Claim 13 the recitation of "said strut extending to said sole plate at the outer side thereof," which was deleted by the previous amendment.

35 U.S.C. §103

The Examiner has rejected Claims 13, 14, and 17-24 under 35 U.S.C. §103(a) as being obvious over Hall in view of the publication WO 95/31950. Applicant traverses this rejection.

The present invention includes the features of "said strut is constructed from a reinforced resin to be resiliently and flexibly configurable" and "said strut extending to said sole plate at an outer side thereof, and anterior of a position of the ankle" (Claim 13 as amended, lines 6-9 generally). These features promote a more normal walking gait. As described in the specification<sup>1</sup>, *inter alia*, on page 5 lines 5-12 and Fig. 3, a preferred embodiment of the present invention helps generate forces based on heel strike and toe strike that approach those of a normal gait.

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<sup>1</sup> All references to page and line numbers of the present application refer to the published PCT application WO 01/34071 AT published on May 17, 2001.

Applicant asserts that Hall does not disclose the feature of said strut extending to said sole plate **at an outer side** thereof, and anterior of the position of the ankle (Claim 13 lines 8-9 as amended, emphasis added). The strut 30, 32, 34, 36 of Hall extends on both sides of the ankle and connects to the footbase 40 on both sides, thereby forming a stirrup. See Hall Figs. 1 and 4, and also the specification, which states:

“In addition, by utilizing the stirrup or yoke surrounding the dorsal portion of the foot and **supporting the foot on either side of the ankle**, twisting and other side motions of the foot are better controlled without adding to the structure and without increasing the discomfort to the patient.

The anterior dorsal ankle foot orthoses of the subject invention **permits the foot to be housed in a stirrup structure** which is placed in front of the ankle and at the dorsal portion of the foot resulting in a much more natural fit and feel to the brace. **By utilizing the more natural stirrup-type support**, the thickness and weight of the support is generally reduced, resulting in less bulk, readily permitting most patients to wear standard footwear and greatly reducing the visibility of the brace. By supporting the foot in the dorsal area, the patient resumes a more normal gait when walking and performing other activities.” (See Hall at col. 2, line 53 through col. 3 line 2, emphasis added).

The design of Hall therefore teaches away from the present invention by utilizing the stirrup-type support strut. This is also emphasized by another feature of the present invention described in the specification on page 1 lines 29-30, which discloses that the orthosis of the present invention is flexible in the region of the ankle and thus permits a degree of ankle flexibility that promotes a more normal walking gait. The stirrup-type support strut of Hall prevents any such flexibility or side motion. Indeed, Hall teaches a wider side member 34 on the inside rather than the outside, as shown in Fig. 1. Therefore, Hall either alone or in combination with other references does not disclose each and every feature of the present invention.

Another feature of the present invention as recited in Claim 13 is that “said strut is constructed from a reinforced resin to be resiliently and flexibly configurable” (Claim 13 lines 6-7). The specification draws attention to the difference between ‘flexible’ and ‘inflexible’ materials on page 2, lines 1-8, as applicable to the present invention. The present invention includes an inflexibly rigid longitudinal stiffener, and a resiliently and flexibly configurable strut.

The Examiner asserts that publication WO 95/31950 teaches the use of two joined areas of a brace made of two different materials with different degrees of rigidity, and also that it would have been obvious to substitute this feature of publication WO 95/31950 with Hall to achieve a degree of flexion as suggested by Hall. Applicant respectfully disagrees with both these assertions.

First, Applicant asserts that publication WO 95/31950 does not disclose or teach any flexibility for the wrist, in fact, it specifically teaches immobilization of the wrist, see page 3 lines 9-12 wherein it states: “[The orthosis] must be rigid in other areas so as to give an adequate **immobilisation** [sic] of the wrist ...” (emphasis added). The flexibility described in publication WO 95/31950 refers to the cloth frame 1, which is wrapped around the wrist and lower arm. However, the reinforcement element 2a-2b (which the Examiner is comparing to the strut of the present invention) is rigid with no disclosure of providing a degree of flexibility. Further, while publication WO 95/31950 discloses using different number of layers of material in part 2a and 2b of the reinforcement element, this is to provide different amounts of **strength**, not rigidity. See page 3 lines 30-39. Therefore publication WO 95/31950 does not disclose any feature of providing differing levels of flexibility, in stark contrast to the present invention, which includes differing levels of flexibility to achieve the goal of a more natural gait when walking.

Second, and assuming arguendo, Applicant asserts that even if publication WO 95/31950 did disclose reinforced resin materials to achieve different levels of flexibility, it would not be obvious to combine this feature with the teachings of Hall. Hall teaches using a thermoplastic material (which by its nature is much more flexible than the glass reinforced resin), and discloses bending in the area 28. The substitution of a resin reinforced material for the stirrup of Hall, as suggested by the Examiner, is unworkable. The width of the stirrup of Hall (32,34) means that bending thereof is inevitably by buckling of the thermoplastic. The resin reinforced materials of W095/31950 cannot buckle, rather they will remain comparatively inflexible, in which case the stirrup of Hall will not deform as intended.

Further to the above, note that Hall bends at the region 28, which is rather wide (see Fig. 4). Use of glass reinforced resin here, even if very thin, would result in a relatively rigid joint. If the bending region is made very thin to increase flexibility there is a risk of breakage and patient injury.

Accordingly, Applicant asserts that neither Hall nor WO 95/31950 disclose each and every feature of the present invention as claimed in Claim 13, and that it is also unworkable to combine the teachings of Hall and publication WO 95/31950. Therefore, Applicant asserts that Claim 13 as amended is allowable over the cited prior art. Applicant asserts that Claims 14-25 depend upon allowable Claim 13 and therefore are also allowable.

The Examiner has rejected Claims 15 and 24-25 under 35 U.S.C. §103(a) as being obvious over Hall combined with other references. Applicant traverses this rejection and states that these claims depend from allowable Claim 13 and are therefore allowable.

### **CONCLUSION**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such action is hereby solicited. The Examiner is invited and encouraged to telephone the undersigned at the number below with any questions or concerns in furtherance of the prosecution of the present application.

Please charge any deficiency as well as any other fees which may become due at any time during the pendency of this application, or credit any overpayment of such fees to deposit account No. 50-0369. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge deposit account No. 50-0369 therefore.

Respectfully submitted,



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